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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 677,042	09 29 2000	Yasuyuki Nozaki	07898-059001	1694

7590 05 15 2003
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EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/677,042

Applicant(s)

NOZAKI ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 27 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 7-10 and 12-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 11 is/are rejected.
- 7) ☒ Claim(s) 5 and 6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 February 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. All objections and rejections not reiterated below are hereby withdrawn.

Election/Restrictions

Search and consideration of the prior art has shown that a search for methods of displaying gene expression patterns routinely provides results wherein experiment cases are conducted in or analyzed for time dependency. S this limitation does not require a separate search, claim 5 is hereby rejoined with claims 1-4, 6, and 11.

Claims 7-10 and 12-15 are again withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 5.

An action on the merits of claims 1-6 and 11 follows.

Claim Objections

Claim 6 is objected to because of the following informalities: the term "display" in line 1 should be --displaying--. The term --an" should be inserted before "individual's" in line 2. Claim 5 is objected to because the term "pattern" in line 1 should be --patterns--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 2-4 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's arguments filed 2/27/03 have been fully considered but they are not persuasive. Applicant's arguments are addressed below, where appropriate.

Amended claim 2 recites "wherein comparing the expression patterns of two different genes to determine whether are identical..." This is grammatically incorrect sentence construction, which is assumed by the examiner to be a typographical error. Due to the omission of a subject for "are identical", it is unclear what is determined to be identical; i.e. the expression patterns or the genes, therefore the claim is indefinite. This rejection may be overcome by inserting the appropriate noun before the phrase "are identical" in line 2. Applicant is advised that inserting the term "they" will not overcome this rejection.

Claim 2 recites "comparing the expression patterns of two different genes" in line 2. It is unclear if applicant intends --several expression patterns of two different genes-- or --an expression pattern from each of two genes--, therefore the claim is indefinite. Applicant states on page 5 of the response filed 2/27/03 that applicants agree with an interpretation of claim 2 as "comparison of a reference value to a single expression pattern from each of two different genes to determine whether the expression patterns of the two different genes are identical"; however, the claim no longer recites any limitation with regard to a reference value but merely recites comparing expression

patterns of genes, therefore this interpretation is not a valid one for the amended claim. Further, it is noted that an examiner's interpretation is merely one way of viewing an indefinite claim in order to further examination. The examiner's interpretation is NOT an indication of what *applicants* intend as the metes and bounds of a claim. Thus, the limitations intended by applicant for claim 2 are still unclear for the various reasons set forth above, and amended claim 2 is indefinite. It is noted that comparison of two expression patterns to each other to establish identity, in the absence of comparison to a reference value, may be neither supported nor enabled by the instant specification. However, as it is unclear what method steps and/or limitations applicant actually intends in claim 2, as set forth above, the claim is rejected herein only for indefiniteness.

Claims 3 and 4 each recite a step of displaying genes according to a predetermined display format, then recite a change in expression format for the displayed genes. Applicant amended claims 2 and 3 to recite "whereby ...genes have the same (different) expression pattern(s) ... but change to..." This amendment does not clarify whether the limitations following "whereby" are intended to be a method step, or whether the "change" in expression pattern is intended to be a limitation of the expression pattern itself, is intended to be a limitation of the "two or more different genes", or is intended to be a limitation of the "predetermined display format" of the displaying step, therefore the claims are still indefinite. The examiner suggests rewriting each claim so that any intended method steps are recited in active, positive language, and such that any other claim limitations are clear; e.g. --displaying results for two or more different genes according to the predetermined display format wherein the genes

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are ones which....-- Note that language such as "genes are ones which" clearly indicates what the limitation following the phrase is intended to limit. Similar language for limiting expression patterns would be --wherein the expression patterns are ones which--. Applicant should note that these are suggestions ONLY for claim format and clarity of language, not for claim limitations. Applicant is again reminded that it should be made clear, for each limitation recited, *what* applicant is intending to limit.

Amended claim 11 recites the phrase "that repeats ... and displays..." at the end of the claim. It is unclear what is intended to repeat and display; i.e. the apparatus of the preamble, the inputting means, or the arithmetic unit, therefore the claim is indefinite. Further, it is noted that "repeats" and "displays" appear to be method steps; however, claim 11 is directed to an apparatus. As an apparatus (product) is not a method, it is unclear what limitations of the product/apparatus applicant actually intends, and the claim is further indefinite. Applicant is advised that an apparatus may comprise --means for repeating-- and --means for displaying-- or may comprise --repeating means-- and --displaying means--.

Claim Rejections - 35 USC § 102

Claims 1-6 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by WEN et al. (PNAS (1/1998) vol. 95, pp. 334-339).

Applicant's arguments with respect to claim 1-4, 6, and 11 have been considered but are moot in view of the new ground(s) of rejection.

WEN teaches a method of displaying gene expression patterns wherein a first axis represents genes and a second axis represents experiment cases, genes are clustered based on a reference value (time of development), and the same genes are reclustered in a forward or reverse direction while changing the reference value (Figure 3a and 3c), thereby anticipating claims 1 and 4. WEN teaches that his system can be used to correlate expression of genes during the same or different developmental stages (i.e. to determine if expression patterns for multiple genes are identical), and can distinguish expression patterns which start out the same but become different and those which start out as different patterns then change to the same pattern (pages 336-338 and Table 1), thereby anticipating claims 2-3 and 5. As WEN's expression patterns all relate to development of neural tissue, his "experiment cases" are necessarily "states" of an individual's tissue, and claim 6 is anticipated. WEN's method is a computer-implemented one and he teaches that he uses a software package for implementing his method, thus WEN's computer system for running his method necessarily comprises an input means and an arithmetic unit. As WEN's method requires repeating clustering, as set forth above, and WEN shows graphs (output) of his results, WEN's system inherently comprises means for clustering and means for displaying his results, thus claim 11 is also anticipated.

Conclusion

Claims 1-6 and 11 are rejected; claims 5 and 6 are also objected to. Claims 7-10, and 12-15 are again withdrawn.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN
PATENT EXAMINER

Marjorie A. Moran

mam
May 13, 2003